

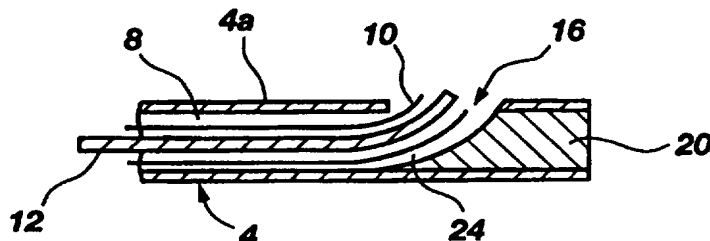


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61M 25/00	A1	(11) International Publication Number: WO 97/44083 (43) International Publication Date: 27 November 1997 (27.11.97)
(21) International Application Number: PCT/US97/08639 (22) International Filing Date: 21 May 1997 (21.05.97) (30) Priority Data: 08/653,291 24 May 1996 (24.05.96) US (71) Applicant: SARCOS, INC. [US/US]; 360 Wakara Way, Salt Lake City, UT 84108 (US). (72) Inventors: JACOBSEN, Stephen, C.; 274 South 1200 East, Salt Lake City, UT 84102 (US). LIPPERT, John; 9055 Jeremy Road, Park City, UT 84098 (US). (74) Agents: THORPE, Calvin, E. et al.; Thorpe, North & Western, L.L.P., Suite 200, 9035 South 700 East, Sandy, UT 84070 (US).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>

(54) Title: CATHETER/GUIDE WIRE STEERING APPARATUS AND METHOD**(57) Abstract**

A catheter/guide wire steering mechanism includes a catheter (4) having a proximal end, a distal end, and sidewalls which define at least the first lumen (18). An opening (16) is formed in a sidewall (4a) of the catheter, near the distal end thereof in communication with the first lumen. A plug (20) is disposed in the catheter at the distal end thereof and includes a curved surface (24) for deflecting and directing out the opening, the leading end of a guide wire (12) (or other catheter) inserted into the lumen at the proximal end of the catheter. This enables guiding the guide wire laterally from the catheter either into a passageway branching from the main passageway into which the catheter is inserted, or to perforate a sidewall of the main passageway.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

5

CATHETER/GUIDE WIRE STEERING APPARATUS AND METHOD

10

BACKGROUND OF THE INVENTION

This invention relates to a side exit catheter through which a guide wire and/or another catheter may be steered laterally of the catheter.

15 Catheter guide wires have been used for many years to guide catheters to desired target locations in the human bodies vasculature. Typical guide wires are from about 155 centimeters to 195 centimeters in length and are made of stainless steel, with a platinum alloy coil spring soldered or otherwise attached to the stainless
20 steel wire at the distal end. The use of platinum for the coil spring provides radiopacity for X-ray viewing during navigation of the guide wire in the body and the coil spring reduces likelihood of puncture by the guide wire. Of course, other soft tips may be used for the
25 leading end of the guide wire, the purpose being to reduce the likelihood of puncture of the anatomy.

Navigation through the anatomy is typically achieved by viewing the guide wire in the body using X-ray fluoroscopy. The guide wire is inserted into a
30 vessel or duct (along with the catheter if desired) and moved therethrough until the guide wire tip reaches the desired vessel or duct branch. The proximal end of the guide wire is then rotated or torqued hopefully to a point where a curved tip of the guide wire is pointed
35 toward the desired branch for advancement into the

branch. The guide wire, with the catheter threaded thereover, are then advanced further until the tip of the guide wire reaches the target location. The catheter is then moved to the target location, following the guide wire. Once the catheter is in place, the guide wire may be withdrawn, depending upon the therapy to be performed.

If a vessel or duct branch extends from the main vessel or duct at an especially sharp angle, it becomes very difficult and in many cases impossible to simply rotate the curved tip of the guide wire so as to allow advancement of the tip into the branch. Of course, it would be desirable to provide apparatus for easily accommodating the movement of guide wires into angled branches of a vessel or duct and into other tortuous and twisting vasculature passageways.

SUMMARY OF THE INVENTION

It is an object of the invention to provide an improved apparatus and method for steering a guide wire and/or catheter through vasculature passageways.

It is also an object of the invention to provide such apparatus and method which allows for directing a guide wire into vessels or ducts which branch off from primary vessels or ducts at sharp angles.

It is a further object of the invention to provide such apparatus and method in which guide wires can be guided into branch vessels or ducts at angles up to 135 degrees and beyond.

It is another object of the invention to provide such apparatus which is simple in design and construction.

It is still a further object of the invention to provide such a method which is relatively easy to carry out.

It is also an object of the invention to provide such apparatus and method which allows for side exit

from a vessel or duct, and entry via piercing into other tissue or other ducts.

The above and other objects of the invention are realized in a specific illustrative embodiment of a catheter/guide wire steering apparatus which includes a catheter having a proximal end, a distal end, and the sidewalls which define at least one lumen, an opening in a sidewall of the catheter, near the distal end thereof, in communication with the lumen, and a deflection element disposed in the catheter at the distal end thereof for deflecting and directing out the opening, the leading end of the guide wire inserted into the lumen at the proximal end of the catheter, to thereby enable guiding the guide wire laterally from the catheter.

In accordance with one aspect of the invention, the catheter includes a second lumen extending the length of the catheter for receiving a second guide wire to guide the catheter to a target location in a vasculature passageway. Also, an inflatable balloon is disposed at the distal end of the second lumen for expanding when contrast agent and/or saline solution or other liquid is forced into the second lumen, to force the opening in the first lumen against a sidewall of a vasculature or duct passageway into which the catheter is inserted. In this position, a guide wire may be inserted in the first lumen either to pierce the vasculature passageway sidewall or to travel into a branch duct branching from the vasculature passageway at the location of the first lumen opening.

BRIEF DESCRIPTION OF THE DRAWINGS

The above and other objects, features and advantages of the invention will become apparent from a consideration of the following detailed description presented in connection with the accompanying drawings in which:

FIG. 1 is a side, fragmented, cross-sectional view of a catheter/guide wire steering apparatus made in accordance with the principles of the present invention;

FIG. 2 is a side, fragmented, cross-sectional view of another embodiment of catheter/guide wire steering apparatus, also made in accordance with the principles of the present invention;

FIG. 3 is a side, fragmented view of the proximal end of a catheter, with luer adapters, in accordance with the present invention;

FIG. 4 is a side, fragmented, cross-sectional view of a catheter/guide wire steering apparatus, especially suitable for sidewall puncture of a body duct or passageway;

FIG. 5 is an end cross-sectional view of a nerve sheath; and

FIG. 6 is a side, fragmented, cross-sectional view of a catheter/guide wire steering apparatus, especially suitable for treatment of aneurysms.

DETAILED DESCRIPTION

Referring to FIG. 1, there is shown a side, fragmented, cross-sectional view of the distal end of a catheter 4 having a lumen 8, into which is threaded a smaller catheter 10, inside of which is a guide wire 12. An opening 16 is formed in a sidewall 4a of the catheter 4, for communication with the lumen 8. A plug 20 is disposed in the end of the catheter 4 and includes a gradually curving surface 24 formed on the sidewall of the catheter 4 opposite the opening 16, to deflect and direct both the smaller catheter 10 and the tip of the guide wire 12 laterally out of the opening 16. The plug 20, advantageously, is a radiopaque and lubricous polymer for ease of X-ray visualization and entry and exit. (A radiopaque band could also be used, as well as an MRI detectable plug or band for viewing during MRI procedures.)

In the manner described, a guide wire can be deflected and directed laterally from a catheter to a branch vessel or duct. This is accomplished by first threading the catheter through a vasculature passageway until the opening 16 is positioned adjacent a branch vessel or duct into which the guide wire 12 (and smaller catheter 10) is to be directed. Then, the guide wire 12 and smaller catheter 10 would be threaded through the catheter 4 until the leading tip of the guide wire 12 exited the opening 16 and entered the branch vessel or duct. The guide wire 12 could then be moved further to the desired target location, along with the smaller catheter 10.

Alternatively, the catheter 4 and guide wire 12 could be utilized without the catheter 10, to direct the guide wire into the branch vessel or duct. Then, the catheter 4 could be removed and catheter 10 threaded over the guide wire 12 to the desired location in the branch vessel or duct.

For the configuration shown in FIG. 1, the lumen 8 could advantageously have a diameter of from about .008 inches (for example, if guide wire only is to be inserted therein) to .078 inches (for example, if catheter and guide wire are to be inserted therein)--two preferred diameters being .020 inches and .042 inches, respectively. The exterior diameter of the catheter 10 could advantageously be from about .012 inches to .074 inches, with a preferred diameter being .038 inches, with the lumen of the catheter 10 being from about .008 inches to .065 inches in diameter, with a preferred diameter being .020 inches.

FIG. 2 shows a side, fragmented, cross-sectional view of a two-lumen catheter 30 made in accordance with the present invention. The catheter 30 is shown partially inserted into a body duct 34 having a branch duct 38.

The catheter 30 includes two lumens 42 and 46, with lumen 46 extending rearwardly a greater distance than lumen 42 and about which a torquing chuck 50 (and luer adapter) is disposed. (Of course, the torquing chuck 50 could be placed distally ahead of the branching of the lumens 42 and 46.) Formed in the distal end of the lumen 42 is a deflecting end wall 54 which is shaped similar to the plug 20 of FIG. 1, to deflect and direct a guide wire 58 inserted in the lumen 42 out of a side opening 62 of the catheter 30. A longitudinal slit (not shown) in the wall of lumen 42 could be provided to allow "change out" of the guide wire 58.

Coupled at the distal end of the catheter 30 to communicate through an opening 66 with the lumen 46 is a balloon 70. The balloon 70 is located on the opposite side of the catheter 30 from the opening 62 so that when inflated, it would tend to force the opening 62 toward the opposite wall of the duct 34 and, in this case, toward the branch duct 38. Thus, when the catheter 30 were threaded to the desired location in the duct 34, adjacent the branch duct 38, the balloon 70 would be inflated through the lumen 46 to cause the distal end of the catheter 30 to deflect or bend towards the branch duct 38. (If greater bending or deflection of the catheter 30 is desired, the balloon 70 and lumen 46 could be moved or extended more forwardly of lumen opening 62 so that greater pivoting and thus deflection of the distal end of the lumen 42 is achieved. Also, tapering the balloon 70 to be larger forwardly of the opening 62, increases the deflection angle.) This bending, along with a preformed curve 42a formed in the distal end of the catheter 30, and deflecting end wall 54, all serve to position the opening 62 against the opening to the branch duct 38 so that when the guide wire 58 is inserted into the lumen 42, the leading end of the guide wire will emerge from the opening 62 and move into the branch duct 38. The inflation of the

balloon 70 may be adapted to occlude, in vessel 34, the flow of blood and medication or agents (particles, etc.) which may have been injected into the blood stream purposely or accidentally, or may be adapted to specifically not occlude.

Advantageously, balloon 70 may be made of a plastic material such as latex or, if greater rigidity is desired, it could be made of polyethylene, or similar plastic material.

A third lumen could be formed in the catheter 30 and used to initially thread the catheter to the desired location adjacent the branch duct 38 by threading this third lumen over a guide wire (not shown) which had been previously inserted in the main duct 34. However, if the primary vessel or duct 34 is large, or otherwise easily accessible, the catheter 30, with guide wire 58 partially threaded in lumen 42 and/or a guide wire partially threaded in lumen 46 may provide sufficient stiffness to allow insertion and guidance to the desired location. Also, a guide wire (not shown) partially inserted into lumen 46 may also suffice.

Advantageously, the diameter of lumen 42 is from about .008 inches to .078 inches and the diameter of lumen 46 is from about .012 inches to .040 inches. As in the FIG. 1 embodiment, a catheter could be used along with, i.e. threaded over, the guide wire 58.

FIG. 3 shows the proximal end of a two-lumen catheter 80 in which one of the lumens 84 is flared laterally from the other lumen 88 to allow for more convenient access to the lumen 84. Disposed on the proximal ends of each of the lumens are luer adapters 92 and 96 for attaching medication supply devices and the like.

FIG. 4 shows a side, fragmented, cross-sectional view of another two-lumen catheter 100, inserted in a vein 104, carried by a nerve sheath 106 (shown in cross-sectional view in FIG. 5). The object of the use of

catheter 100 is to allow puncture of a wall of the vein 104 to allow introduction of anesthesia or other medication into the nerve sheath 106, without puncturing or damaging arteries or nerves also contained within the
5 nerve sheath.

The catheter 100 includes two lumens 108 and 112, with the lumen 108 curved (using a deflecting end wall 114) at the distal end to exit through a side opening 116 formed in the catheter 100. Coupled over the distal
10 end and opening 120 of the lumen 112 is a balloon 124 which, similarly to the arrangement of FIG. 2, when inflated forces the opening 116 against a sidewall of the vein 104. Inflation of the balloon 124 also serves to occlude the vein 104 and this aids in slowing the
15 return of inadvertently injected medication to the heart. Varying the position of the balloon 124 relative to the opening 116 serves to vary the deflectability of the distal end of the catheter 100, as discussed earlier.

The catheter 100 is inserted in the vein 104 to the desired location and then when the balloon 124 is inflated to force the opening 116 against the sidewall of the vein, a perforating guide wire 128 is inserted in the lumen 108 and out the opening 116 to puncture the
20 sidewall of the vein 104. Medication such as anesthesia would then be supplied through lumen 108 to flow through the perforation in the sidewall of the vein 104 into the nerve sheath, for example. Alternatively, guide wire 128 could be a laterally flexible "needle" or cannula,
25 and the medication could be delivered through that.

With the configuration of FIG. 4, a third lumen (shown by dotted line 132) might be provided to allow introduction of medication into the vein 104 distal to the occluder balloon 124 to thus provide systemic blood
35 access.

The diameter of the lumen 108 might advantageously be from about .008 inches to .042 inches, the diameter

of lumen 112 might advantageously be from about .008 inches to .018 inches, and the diameter of lumen 132 might advantageously be from about .010 inches to .080 inches.

5 FIG. 6 shows another use of a side exit catheter in a situation where an aneurysm 150 has developed at the intersection of three vessels 154, 156 and 158. A side exit catheter 160, as previously described, is inserted in vessel 156 until the tip and the exit opening are
10 disposed at the intersection of the vessels, with the opening generally facing the aneurism 150, and the distal end of the catheter 160 safely resting in vessel 158 (or vessel 154 if the catheter is curved in the opposite direction). A wire 164 with a coil 164a may
15 then be inserted into the lumen of the catheter and threaded upwardly, out the side exit opening and into the aneurysm 150. This allows access to the aneurysm without threat of puncture by the catheter tip. The side exit can now be used to deploy coils or other
20 devices or agents into the aneurysms.

 In FIG. 6, catheter 160 could be provided with an occlusion-type balloon, as previously discussed, so that when inflated, it would occlude vessel 158 or vessel 154 while treating the aneurysm. Also, two balloon
25 catheters could be used so that both vessels 154 and 158 could be occluded while the treatment process proceeded. Such occlusion would protect against embolic or other materials traveling down the vessels during treatment. An additional lumen could be provided in catheter 160 to
30 thereby allow supply of blood beyond the occlusion from vessel 156 to vessel 158 and/or vessel 154.

 In the manner described, side-exit catheters may be provided to direct guide wires laterally into side branching ducts or passageways, to allow for perforating
35 a sidewall of a duct or passageway into which the catheter is inserted, or to provide safe access into anatomy such as aneurysms.

To reduce resistance to movement of the catheters discussed above in a vasculature passageway, the surface of the catheters may be coated with a lubricious coating such as silicone-based oil and/or polymer or hydrophilic polymers. Lubricious coatings could also be applied to the lumens of the catheters to reduce resistance to movement of guide wires or other catheters therein.

It is to be understood that the above-described arrangements are only illustrative of the application of the principles of the present invention. Numerous modifications and alternative arrangements may be devised by those skilled in the art without departing from the spirit and scope of the present invention and the appended claims are intended to cover such modifications and arrangements.

CLAIMS

What is claimed is:

1. Catheter/guide wire steering apparatus comprising
5 a catheter having a proximal end, a distal end, and sidewalls which define at least a first lumen,
an opening in a sidewall of the catheter, near the distal end thereof, in communication with the lumen, and
means disposed in the catheter at the distal end
10 thereof for deflecting and directing out the opening, the leading end of a guide wire or catheter inserted into the lumen at the proximal end of the catheter, to thereby enable guiding the guide wire laterally from the catheter.
15
2. Apparatus as in Claim 1 wherein the distal end of the catheter is shapeable to curve in the direction in which the opening faces.
- 20 3. Apparatus as in Claim 1 further including a guide wire for insertion into the lumen at the proximal end of the catheter and exit out the opening thereof, said guide wire having a distal end which is curved laterally.
25
4. Apparatus as in Claim 1 wherein said catheter includes a second lumen extending the length of the catheter, said apparatus further including a balloon means connected to the second lumen at the distal end of
30 the catheter for expanding when liquid is forced into the second lumen, to deflect and force said opening against a sidewall of a vasculature/duct passageway into which the catheter is inserted.
- 35 5. Apparatus as in Claim 4 wherein said catheter includes a third lumen extending from the proximal end

of the catheter to the distal end thereof, beyond the location of the balloon means.

5 6. Apparatus as in Claim 1 wherein said catheter includes a second lumen extending the length of the catheter for receiving a second guide wire to guide the catheter to a target location in a vasculature passageway.

10

7. Apparatus as in Claim 6 wherein the second lumen includes an access opening at the proximal end of the catheter, and wherein the first lumen includes an access opening at the proximal end of the catheter
15 nearer the distal end than the access opening of the second lumen.

20

8. Apparatus as in Claim 7 wherein the access opening of the first lumen includes a luer adapter.

9. Apparatus as in Claim 7 further including a torquing chuck disposed about the second lumen.

25 10. Apparatus as in Claim 7 further including a torquing chuck disposed about the first and second lumens.

30 11. Apparatus as in Claim 6 wherein the first lumen has a diameter of from about .008 inches to .078 inches, and wherein the second lumen has a diameter of from about .012 inches to .040 inches.

35 12. Apparatus as in Claim 1 further including a radiopaque element disposed at the distal end of the catheter.

13. Apparatus as in Claim 1 further including an element disposed at the distal end of the catheter made of a material detectable by MRI.

5 14. Apparatus as in Claim 1 further including a lubricious coating disposed over the exterior of the catheter.

10 15. Apparatus as in Claim 1 further including a lubricious coating disposed over the walls of the lumen.

16. A method of steering a catheter/guide wire in a vasculature passageway comprising the steps of
15 providing a catheter having a proximal end, a distal end, sidewalls which define at least a first lumen, and an opening in a sidewall near the distal end thereof, in communication with the lumen,
20 providing a deflecting means in the catheter at the distal end thereof to deflect and direct out the opening the leading end of a guide wire or catheter inserted into the lumen at the proximal end of the catheter, and
25 inserting a catheter or guide wire into the lumen at the proximal end of the catheter to deflect the leading end of the catheter or guide wire out the opening.

1/2

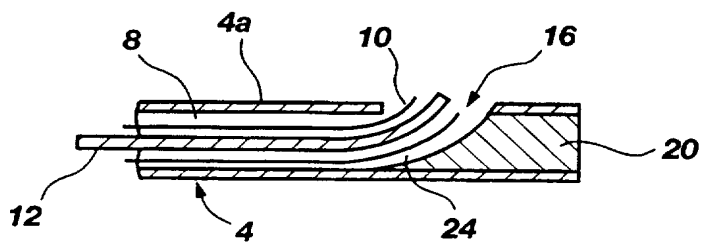


Fig. 1

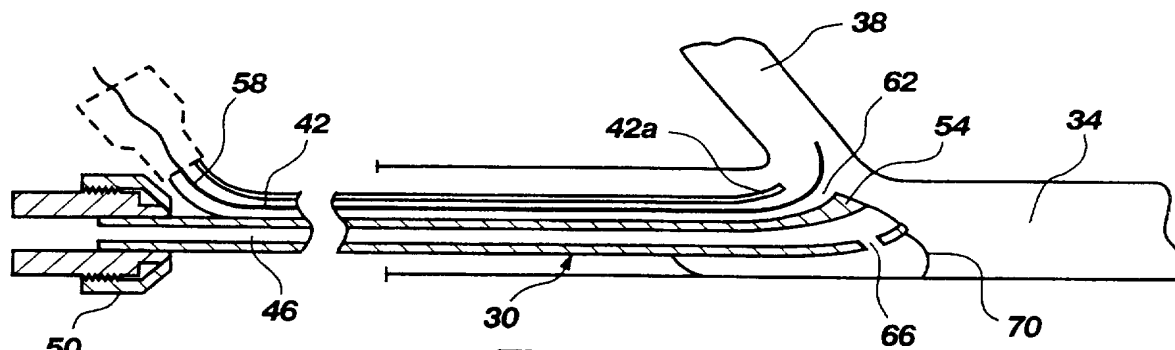


Fig. 2

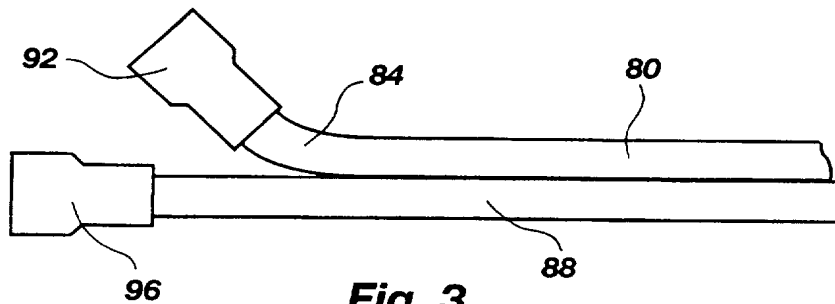


Fig. 3

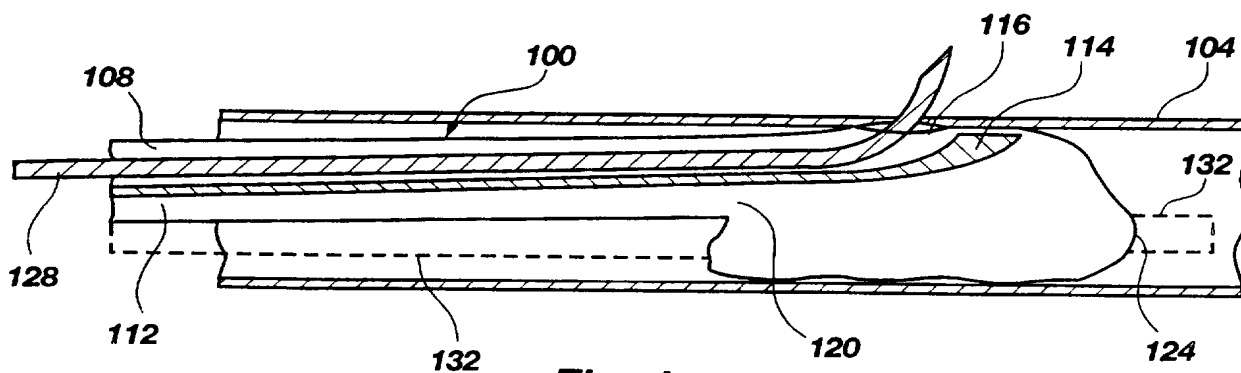
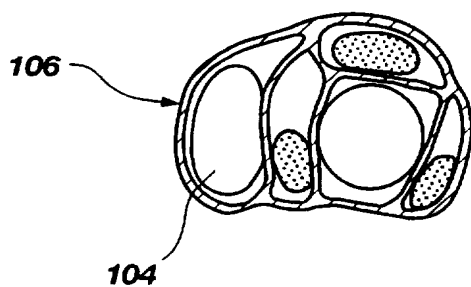
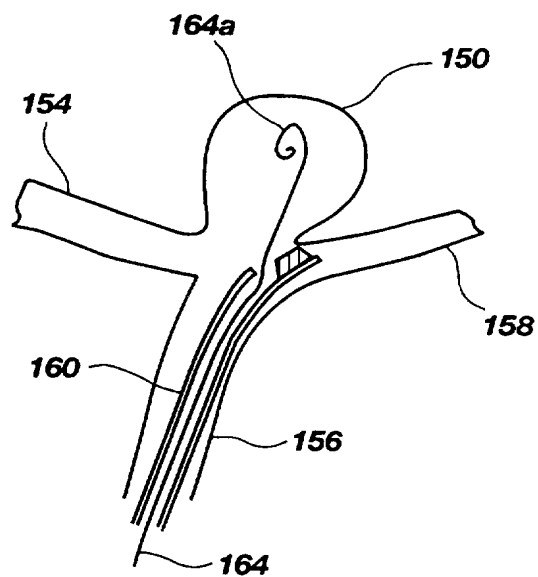


Fig. 4

2/2

**Fig. 5****Fig. 6**

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/08639**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) :A61M 25/00

US CL :604/280

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/192, 194; 604/96, 102, 264, 280

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

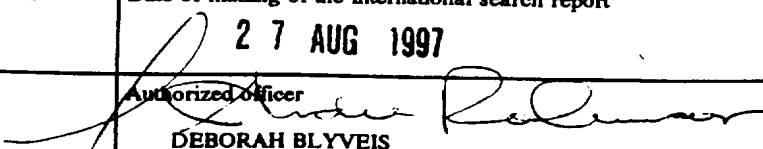
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,413,581 A (GOY) 09 May 1995, Abstract.	1-3, 6, 11, 12, 16 ----- 13
X --- Y	US 5,464,395 A (FAXON et al.) 07 November 1995, Abstract.	1, 4, 5 ----- 7-10
Y	US 4,552,554 A (GOULD et al.) 12 November 1985, Abstract.	7-10
Y	US 5,411,476 A (ABRAMS et al.) 02 May 1995, Abstract.	7-10

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"A" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 05 AUGUST 1997	Date of mailing of the international search report 27 AUG 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer  DEBORAH BLYVEIS Telephone No. 308-2110

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/08639

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,387,235 A (CHUTER) 07 February 1995, Abstract.	13